

2



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,624	07/10/2003	Eduardo Blumwald	529642000500	4097
20872	7590	09/28/2005		
MORRISON & FOERSTER LLP 425 MARKET STREET SAN FRANCISCO, CA 94105-2482			EXAMINER KUMAR, VINOD	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 09/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/617,624

Applicant(s)

BLUMWALD, EDUARDO

Examiner

Vinod Kumar

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 08/19/2005.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The information disclosure statement filed on July 10, 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Legible copies of citations 35-38 are not provided.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims, 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 recite the limitation. "Near normal fatty acid distribution when cultivated in high salt " which is awkward and confusing "Near" and "high" are relative terms that have no definite meaning. "Fatty acid distribution" can suggest location. It is unclear if it is the location, or composition of fatty acids that is being referred to. It is suggested that "Fatty acid distribution" be replaced by --fatty acid composition--.

Claims 3-8 recite the limitation "optimal osmolality", which is awkward and confusing and unclear. Is it the highest concentration of salt that a plant can grow in, or the "optimal" salt concentration that best supports the growth?

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a non-naturally occurring non-halophyte oil crop comprising seeds with normal fatty acid composition when cultivated in high salt, wherein said plant is a transgenic canola comprising a Na<sup>+</sup>/H<sup>+</sup> transporter transgene set forth in SEQ ID NO: 1 driven by CaMV promoter, wherein expression of said gene imparts tolerance to high salt levels without affecting fatty acid composition in transgenic seeds, does not reasonably provide enablement for non-naturally occurring non-halophyte oil crop plants comprising seeds with normal fatty acid distribution when cultivated in high salt, wherein said plant does not comprise SEQ ID NO: 1. The claim (s) contain subject matter which was not described in the specification in such a way as to enable one skilled in the art which it pertains, or with which it is most recently connected, to make and/or use the invention.

The claims are broadly drawn towards a product non-halophyte oil crop plant comprising seed, wherein the said plant seed has normal distribution of fatty acids when cultivated in high salt, or wherein the said plant carries a transgene encoding Na<sup>+</sup>/H<sup>+</sup> antiporter gene operably linked to CaMV promoter, wherein transgene induces secretion of salt out of cytoplasm into vacuole, or wherein transgenic plant is Safflower, or wherein coding strand of SEQ ID NO: 1 encoding Na<sup>+</sup>/H<sup>+</sup> antiporter hybridizes to a

nucleic acid sequence to coding or noncoding copy of SEQ ID NO:1 under stringent conditions, and wherein a plant NHX transporter nucleotide sequence hybridizes to the sequence set forth in SEQ ID NO:1.

The specification indicates over-expressing AtNHX1 transporter gene (SEQ ID NO: 1) from *Arabidopsis* in canola (*Brassica napus*) and cultivating transgenic canola carrying said gene in a nutrient medium having 200 mM sodium chloride concentration. The transgenic plants grew well, flowered and produced seeds (Fig. 1, table 1 and page 24 of specification) in 200 mM sodium chloride nutrient medium. Seed oil content and composition of transgenic seeds harvested from high salt cultivated plants was identical with seeds harvested from wild type plants grown on normal medium (Fig. 5 and page 26 of specification).

However, the specification does not teach non-naturally occurring non-halophyte plants created, for example, by chemical or non-chemical mutagenesis, interspecific hybridization that involves breeding, *in vitro* selection, etc., and which can grow in high salt levels with normal levels of fatty acid composition or content. Claim 1 and the claims dependent from it encompasses any non-naturally occurring non-halophyte oil crop plant seed having normal fatty acid content or composition when cultivated in high salt. The specification only discloses putting AtNHX1 in oil crop plant plants through transformation. However, claim 1 comprises more than just transgenic plants. The specification does not teach the use of other salt tolerant genes, including other members of the plant vacuolar Na<sup>+</sup>/H<sup>+</sup> transporter gene family, in non-halophyte oil crop plants impart salt tolerance. Again, while claim 1 encompasses any

non-naturally occurring oilseed crop plant comprising normal fatty acid composition when cultivated in high salt, the specification does not teach how such plants can be produced through non-recombinant mediated methods, such as, mutagenizing a seed population of wild type oilseed crop plant and selecting for mutants plants that can be cultivated in high salts and comprise seeds with normal composition of fatty acids.

It is well established that random mutagenesis can result in mutation at more than one site in genome, and it is equally established that such unexpected mutations can result in additional phenotype(s) beside the mutant phenotype under investigation. See Chandler et al. (Trends in Plant Science, 8:279-285, 2003), page 1 and paragraph 2). Undue experimentation would be required by a skilled artisan to produce such salt tolerant plants that are non-naturally occurring and comprise seeds with normal composition of fatty acids. Introduction of SEQ ID NO: 1 alone did give tolerance.

Claim 17, encompasses a non-naturally occurring non-halophyte oil crop plant comprising a nucleic acid molecule that hybridizes with SEQ ID NO: 1. However, the hybridizing molecule would not encode an NHX1 coding strand since sequences complementary to SEQ ID NO: 1 would bind.

Further claim 17 encompasses any plant NHX transporter hybridizing to AtNHX1 under moderately stringent conditions to give same phenotype. However, it is well established that under moderately stringent conditions, unrelated nucleotide sequences would bind to a given template sequence. Undue experimentation would be required by one skilled in the art to use unrelated nucleotide sequences.

See Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed.

Art Unit: 1638

Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Given the breadth of the claims encompassing all naturally occurring non-halophyte oil crop plant comprising seeds with normal fatty acid, unpredictability of the art and lack of guidance of the specification, as discussed above, undue experimentation would be required by one skilled in the art to make and use of claimed invention.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards non-naturally occurring non-halophyte oil crop plant comprising seeds with normal fatty acids composition when cultivated in high salt, or wherein the said plant carries a transgene encoding Na<sup>+</sup>/H<sup>+</sup> antiporter gene operably linked to CaMV promoter, wherein transgene induces secretion of salt out of cytoplasm into vacuole, or wherein coding strand of SEQ ID NO: 1 encoding Na<sup>+</sup>/H<sup>+</sup> antiporter hybridizes to a nucleic acid sequence to coding or noncoding copy of SEQ ID NO:1 under stringent conditions, and wherein a plant NHX transporter nucleotide sequence hybridizes to the sequence set forth in SEQ ID NO:1.

However, specification does not describe non-naturally occurring non-halophyte oilseed crop plant comprising seeds with normal fatty acid composition when cultivated

in high salt, wherein said plant comprising genome that was mutagenized to select for high salt tolerant mutant phenotype or said plant comprising *in vitro* selection for salt tolerant non-naturally occurring non-halophyte oilseed crop plant with normal fatty acid distribution when cultivated in high salt, as all these types of non-naturally occurring salt tolerant oilseed crop plant encompasses in claim 1 and the claims dependent from it. The specification does not teach structures all other possible species with identical function as encompassed in claim 1. The only species described is the transgenic non-naturally occurring non-halophyte oilseed crop plant with normal fatty acid distribution when cultivated in high salt, comprising SEQ ID NO: 1 incorporated in the genome of said transgenic plant. The specification also does not describe wide range of non-naturally occurring non-halophyte oilseed crop plants comprising seeds with normal fatty acid composition when cultivated in high salt, wherein said wide range of oilseed crop plant comprise different member(s) of antiporter gene family. The specification does not correlate the structure of any other non-naturally occurring non-halophyte oil crop plant comprising seeds with normal fatty acid composition when cultivated in high salt, except for those plants comprising SEQ ID NO: 1 and nucleotide sequence differing there from by genetic code degeneracy.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide an adequate written description of the genus broadly claimed. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.



The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Dierig et al. (Crop Science, Volume 41, pages 604-605; issued March-April 2001).

The claims 1, 2 and 3 are broadly drawn towards a non-naturally occurring non-halophyte oil crop plant comprising seeds with normal or near fatty acid distribution when cultivated in high salt, wherein the near normal fatty acid distribution is within five percent of the normal distribution, and wherein the high salt is at least 2 times the optimal osmolality for the non-halophyte plant.

Dierig et al. teach selection and isolation of a salt tolerant plant *Lesquerella fendleri* designated "WCL-SL1" that had normal levels of seed oil content when cultivated under high salt, wherein nutrient solution was having 2 times ( $3 \text{ ds m}^{-1}$ ) the electric conductivity or osmolality compared to the optimal osmolality for the non-halophyte plant. See page 604, column 2; page 605. *Lesquerella fendleri* is an important non-halophyte seed oil crop and seed oil content is measure of fatty acid content and its distribution.

Claims 1-6, 9 and 11 are also rejected under 35 U.S.C. 102(b) as being anticipated by Yermanos et al. (Agron. J., 56:35-37, 1964), as evidenced by Francois et al. (Agron. J. 56:38-60, 1964).

Art Unit: 1638

Yermanos et al. teach commercial, and therefore non-naturally occurring salt tolerant varieties of Safflower, an oilseed crop plant. Fatty acid composition of seed oils remained unchanged when grown in low, medium and high salt concentrations. See page 36, table 3; page 37, table 4 and summary. Seeds used by Yermanos et al. for fatty acid composition determination were harvested from salt tolerant Safflower plants grown in nutrient solution having electric conductivity 2, 3, 4 or 5 times (5.2, 8.3, 13 or 15.5  $\text{ds m}^{-1}$ ) the optimal osmolality for the non-halophyte plant. See Yermanos et al., page 35 and introduction, and Francois et al., page 38 and second paragraph.

*Conclusion*

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, William (Gary) G. Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1638

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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